DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Central Region 34916d

New Jersey District
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

July 26, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Freidenrich, Chief Executive Officer
Bio Compression Systems
120 West Commercial Avenue
Moonachie, New Jersey 07074-1703

04-NWJ-16

Dear Mr. Freidenrich:

During an inspection of your establishment located in Moonachie, NJ, from March 2-15, 2004, our investigator determined that your establishment manufactures sequential circulators and compression therapy garments to be used with the sequential circulators. These sequential circulators and compression therapy garments are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100. Furthermore, the draft "Corrective and Preventive Action Plan" (CAPA) that was submitted to our investigator at the close-out meeting does not appear to be adequate. Specifically, the plan is inadequate in that it is not an established procedure which identifies the quality data sources utilized to identify existing and potential sources of nonconforming products and other quality related problems and how this information is reviewed by management. In addition, the CAPA plan does not describe how corrective and preventive actions will be verified or validated to ensure that the action is effective.

   Failure to establish and maintain design control procedures as required by 21 CFR 820.30. These requirements ensure that specific design requirements are met. As described in the Form FDA-483 issued to your firm at the close of the inspection, our investigator found that your design control procedures were deficient in terms of design and development planning, design input, design output, design review, design verification, and design validation.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints and ensuring the complaints are handled in a timely manner (21 CFR 820.198). Specifically, complaint information was destroyed and no complaint investigations were conducted when products were not returned to your firm within a specified time period. In those instances in which no investigation was conducted, you failed to maintain records showing the reason why no investigation was conducted and the name of the person responsible for the decision not to investigate. Furthermore, there is no assurance that complaints are adequately evaluated to determine whether the complaint should also be filed as a Medical Device Report, in that SOP 09-03 was not followed and the "MDR Determining Form" was not completed in all instances. While the form specified in your SOP is not a requirement, there must be an adequate evaluation. These are additional requirements of 21 CFR 820.198.

3. Failure to maintain up-to-date Device Master Records. Specifically, your firm changed the type of pin used in all of your sequential circulators; however, none of the device records were updated to show the current specification as required by 21 CFR 820.181.

Moreover, the Act requires manufacturers of medical devices to obtain marketing approval or clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that newly-introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in the United States. According to our records, you have not obtained marketing approval or clearance for the Sequential Circulator Model 3008. During the inspection, you stated to the FDA investigator your belief that Model 3008 is equivalent to Model 3004, and therefore also covered by the pre-amendment status determination letter that FDA issued to your company in August 1993. However, because of significant changes you have made to the design of Model 3004, the pre-amendment status determination does not apply to the resulting new product, Model 3008. Changes made during the development of Model 3008 include: increasing the number of chambers from [redacted] to [redacted] decreasing the inflation time from [redacted] to [redacted] seconds; decreasing the deflation time from [redacted] to [redacted] seconds; decreasing the cycle time from [redacted] seconds/chamber to [redacted] seconds/chamber; identifying 4 additional garments related to the device design; adding the capability to individually adjust chamber pairs; and providing 4 levels of calibrated gradient pressure.

These changes represent major modifications that could significantly affect the safety or effectiveness of your device. Under FDA regulations at 21 CFR 807.81(a)(3)(i), any change that could significantly affect the safety or effectiveness of a device, including certain changes to the design, material, chemical composition, energy source, or manufacturing process, requires the submission of a premarket notification (also referred to as a "510(k)") in accordance with Section 510(k) of the Act. Because you did not submit a 510(k) to the agency prior to introducing Model 3008 into commercial distribution, this device is misbranded under Section 502(o) of the Act. Until you submit a 510(k) and FDA reviews it and notifies you that your device is substantially equivalent to other legally marketed devices, Model 3008 is also adulterated under Section 501(f)(1)(B) of the Act because the law requires, and you do not have, an approved premarket approval application (PMA) that

shows your new device is safe and effective. For a product requiring premarket review before marketing, the notification required by section 510(k) of the Act is deemed to be satisfied when a PMA is pending before the agency [21 CFR 807.81(b)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA-483, issued at the conclusion of the inspection, may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations found by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market approval applications (PMAs) for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should be sent to Sarah A. Della Fave, Compliance Officer, U.S. Food and Drug Administration, New Jersey District, 10 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District